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(54) Title: MONOCLONAL ANTIBODIES SPECIFIC FOR CARIOGENIC BACTERIA

(57) Abstract: Antibodies, as well as binding fragments and mimetics thereof, that specifically bind to Actinomyces or Lactobacillus cariogenic bacteria are provided. The subject binding agents, e.g., antibodies, fragments and mimetics thereof, etc., are characterized in that they are highly sensitive and specific for their target bacteria. Also provided are methods and devices for screening samples for the presence of cariogenic bacteria. In addition therapeutic treatment protocols and compositions are provided.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/32543

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12P 21/08; C07K 16/00

US CL : 530/388.5, 387.1, 388.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 530/388.5, 387.1, 388.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X | FIRTEL, M. et al. Distribution of antigenic determinants between <i>Actinomyces viscosus</i> and <i>Actinomyces naeslundii</i> . J. Dent. Res. January 1988, Vol. 67, No. 1, pages 15-20, abstract; Materials and Methods; and Results. | 1-4 and 7 |
| --- | | 12 |
| Y | | |
| X | HAPPONEN, R. et al. Comparison of polyclonal and monoclonal antibodies to <i>Actinomyces</i> and <i>Arachnia</i> species. Scand. J. Dental Res. 1987, Vol. 95, pages 136-143, abstract; Materials and Methods; and Results. | 1-4 and 7 |
| --- | | 12 |
| Y | | |
| X | THURNHEER, T. et al. Characterization of monoclonal antibodies for rapid identification of <i>Actinomyces naeslundii</i> in clinical samples. FEMS Microbiol. Lett. 1997, Vol. 150, pages 255-262, abstract; Materials and Methods; Results; and Tables. | 1-4 and 7 |
| --- | | 12 |
| Y | | |

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

09 June 2004 (09.06.2004)

Date of mailing of the international search report

23 JUL 2004

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1 (in part), 2-4, 7, 10 and 12

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US03/32543

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-4, 7-10 and 12, drawn to an antibody that recognizes a cell surface antigen of a cariogenic *Actinomyces* species.

Group II, claims 1, 5-7, 11 and 12, drawn to an antibody that recognizes a cell surface antigen of a cariogenic *Lactobacillus* species.

Claims 8, 9 and 13-30 are unsearchable because of their improper multiple dependency.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of claim 1 is an antibody that recognizes a cell surface antigen of a cariogenic *Actinomyces* species or *Lactobacillus* species. The two antibodies do not share a significant structure or immunologic specificity. Furthermore, the special technical feature is already disclosed in the prior art. For example, Firtel *et al.* (*J. Dental Res.* 67: 15-20, 1988) taught several monoclonal antibodies recognizing cariogenic *Actinomyces* species, and Yutaka *et al.* (JP 406311894A, abstract) taught a monoclonal antibody recognizing *Lactobacillus casei*. Therefore, the special technical feature is not a unifying feature.

Continuation of B. FIELDS SEARCHED Item 3:

DIALOG, WEST, MEDLINE, BIOSIS, EMBASE

antibod? or Ig, Actinomyses, Naselundiii, SWLA4